



DOCKET NO.: P0453.70115US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Sanghvi et al.

Serial No .:

10/821,811

Confirmation No.:

9061

Filed:

April 8, 2004

For: Examiner: PHARMACEUTICAL FORMULATION

Donna A. Jagoe

Art Unit:

1614

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 2007 day of February, 2007.

MAIL STOP AMENDMENT

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:

Edward R. Gates, Reg. No.: \$1,616 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: P0453.70115US01 Date: February 2 2007

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Emily E Zukauskas

MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case.

No fee or certification is required.

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Conf. No.: 9061

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Serial No.	Filing Date	Inventor(s)	Docket No.
11/441,395	May 25, 2006	Doshan	*P0453.70119US01
11/441,452	May 25, 2006	Wagoner et al.	*P0453.70120US02

^{*}A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report or other communication from a corresponding International or Foreign National Application.

Serial No.	Mailing Date	Type(s) of Communication	Docket No.
SG 200506463-9	May 4, 2006	Written Opinion	P0453.70115SG00

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application; 1100858.1

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Conf. No.: 9061

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:

Edward R. Gates, Reg. No. 31,616 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: P0453.70115US01

Date: February 20, 2007

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FORM PTC)-1449/A and B (m	odified	1 PTO/SR/08)	APPLICATION NO.:	10/821,811	ATTY. DOCKET NO.: P0453 70TTSUS01
FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				FILING DATE:	April 8, 2004	CONFIRMATION NO.: 9061
				APPLICANT:	Sanghvi et al.	B 23 7007 5
				GROUP ART UNIT:	1614	EXAMINER: Donna A. Vege
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EXAMINER:	DATE CONSIDERED:

[#] EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)			APPLIC	CATION NO.: 10/821,811	ATTY. DOC	CKET NO.: P0453.70115US01		
INFORMATION DISCLOSURE		FILING DATE: April 8, 2004		CONFIRMATION NO.: 9061				
	STATEMENT BY APPLICANT		APPLIC	APPLICANT: Sanghvi et al.				
Sheet	Sheet 2 of 4				GROUP ART UNIT: 1614		EXAMINER: Donna A. Jagoe	
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		OTHER ART — NON PATENT LITERATURE DOCUMENTS	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Sheet 4 of 4 Of 4 GROUP ART UNIT: 1614 EXAMINER: Donna A. Jagoe YUAN et al., Methylnaltrexone changes gut motility and transit time in chronic methadone- maintained subjects. Anesth Analg. 1999;88: 51-424. Abstract \$404. YUAN et al., Antagonism of chronic opioid-induce gut effects. Anesth Analg. 2000;90:S1-523. Abstract \$479. YUAN et al., Pharmacokinetics of intravenous vs. oral methylnaltrexone: evidence for direct gut effects. Anesth Analg. 2001;92: S1-363. Abstract \$274. YUAN et al., Oral methylnaltrexone reverses morphine-induced changes in gastrointestinal motility. Anesthesiology. 1995 Sep;85(3A). Abstract A335. YUAN et al., Oral methylnaltrexone reverses chronic opioid-induced constipation. Anesthesiology. 2000 Sep;93(3A). Abstract A-372. YUAN et al., Subcultaneous methylnaltrexone prevents morphine-induced delay in gut transit time: a clinical trial. Anesthesiology. 2001;95. Abstract A-963. YUAN et al., Subcultaneous methylnaltrexone prevents morphine-induced delay in gut transit time: a clinical trial. Anesthesiology. 2001;95. Abstract A-963. YUAN et al., Dese-related effects of oral acetaminophen on cold-induced pain: a double-blind, randomized, placebo-controlled trial. Clin Pharmacol Ther. 1998 Mar;63(3):379-83. YUAN et al., Gastric effects of mu-, delta- and kappa-opioid receptor agonists on brainstem unitary responses in the neonatal rat. Eur J Pharmacol. 1996 Cat 24;34(1-2):27-32. YUAN et al., Gurantilla and transit changes in patients receiving long-term methadone maintenance. J Clin Pharmacol. 1998 Nov;38(11):1017-20. YUAN et al., Tolerabilly, gut effects, and pharmacokinetics of methylnaltrexone as a novel perplement opioid antagonism of gastrointestinal opioid effects. Reg Anesth Pain Med. 2000 Nov-Dec;25(6):639-42. YUAN et al., Pain control with side effects effects of methylnaltrexone as a novel peripheral opioid antagonism of gastrointestinal opioid effects on methylnaltrexone as a novel peripheral opioid antagonist. Assoc Univ	FORM PTO-1449/A and B (modified PTO/SB/08)	APPLICATION NO.: 10/821,811	ATTY. DOCKET NO.: P0453.70115US01
Sheet 4 of 4 GROUP ART UNIT: 1614 EXAMINER: Donna A. Jagoe YUAN et al., Methylnaltrexone changes gut motility and transit time in chronic methadone- maintained subjects. Anesth Analg. 1999;88: S1-424. Abstract S404. YUAN et al., Antagonism of chronic opioid-induce gut effects. Anesth Analg. 2000;90:S1-523. Abstract S479. YUAN et al., Pharmacokinetics of intravenous vs. oral methylnaltrexone: evidence for direct gut effects. Anesth Analg. 2001;92: S1-363. Abstract S274. YUAN et al., Oral methylnaltrexone reverses morphine-induced changes in gastrointestinal motility. Anesthesiology. 1995 Sep.85(3A). Abstract A527. YUAN et al., Oral methylnaltrexone reverses morphine-induced constipation. Anesthesiology. 2000 Sep.93(3A). Abstract A-872. YUAN et al., Coral methylnaltrexone prevents morphine-induced delay in gut transit time: a clinical trial. Anesthesiology. 2001;95. Abstract A-963. YUAN et al., Botelynaltrexone prevents morphine-induced kaolin intake in the rat. Anesthesiology. 2003;99. Abstract A-922. YUAN et al., Dose-related effects of oral acetaminophen on cold-induced pain: a double-blind, randomized, placebo-controlled trial. Clin Pharmacol Ther. 1998 Mar;63(3):379-83. YUAN et al., Gastric effects of mu-, delta- and kappa-opioid receptor agonists on brainstem unitary responses in the neonaltal rat. Eur J Pharmacol. 1996 Oct 24;314(1-2):27-32. YUAN et al., Gastric effects of low-dose morphine on gastric emptying in healthy volunteers. J Clin Pharmacol. 1998 Nov;38(11):1017-20. YUAN et al., Tolrability, gut effects, and pharmacockinetics of methylnaltrexone following repeated intravenous administration in humans. J Clin Pharmacol. 2005 May;45(5):538-46. YUAN et al., Opioid analgesia without gut side effects. Effects of methylnaltrexone as a novel peripheral opioid antagonism of gastrointestinal opioid effects. Reg Anesth Pain Med. 2000 Nov- Dec;25(6):639-42. YUAN et al., Pain control with side effects: effects of methylnaltrexone as a novel peripheral opioid antagonism of gastrointestinal opioi	•	FILING DATE: April 8, 2004	CONFIRMATION NO.: 9061
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